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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427
24247	7590	11/17/2003	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/081,953

Applicant(s)

HENNEN ET AL.

Examiner

Stacy B Chen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are ~~allowed~~ is free of the prior art of record SBE 11/13.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Applicant's amendment filed September 5, 2003 is acknowledged and entered. Claims 1-22 are pending and examined.
2. The rejection of claims 7-10 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendment. The rejection of claims 7-12 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment.

#### ***Claim Rejections - 35 USC § 112***

3. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is drawn to a method of eliciting a T-cell mediated immune response wherein the composition administered strengthens the immune system of the animal. It is not clear how or what aspect of the "strength" of the immune system can be measured. Clarification is required.

#### ***Claim Rejections - 35 USC § 102***

4. Upon further consideration of the claims and the prior art of record, the following new prior art rejection is applied. The Office regrets any inconvenience to Applicant.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-3, 7-16, 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokoro (5,080,895). The claims are drawn to a method for eliciting a T-cell mediated immune response in an animal, comprising administering transfer factor. The transfer factor is generated by a non-mammalian source animal's egg in response to a T-cell mediated immune response to an antigenic agent. The transfer factor molecules have molecular weights of about 4000-5000 Daltons.

Tokoro teaches a method of eliciting an immune response by administering a transfer factor-like component. The transfer factor-like component is produced from eggs of a hen that has been immunized against an antigen. The transfer factor-like component is recovered from a fraction of at most 10,000 in molecular weight (abstract).

In the Declaration of William J. Hennen, Ph.D., submitted December 5, 2001 in parent application USSN 09/667,147 (now patent 6,468,543), Dr. Hennen elaborates on the meaning of the "transfer factor-like component" disclosed in Tokoro (paragraph 13 of the declaration). One of the references cited by Tokoro provides the background of the term "transfer factor-like component". The Dunnick reference referred to by Tokoro concludes that "no direct relationship has been established between TFLA (transfer factor-like activity) and in vivo transfers of cellular immunity". Further, Dr. Hennen says that the antigen used by Tokoro to immunize the hens would not have resulted in a T-cell mediated immune response, merely a B-cell response to ETEC (paragraph 21 of the declaration).

Therefore, given the teachings of Tokoro and the Hennen declaration of record in the parent application USSN 09/667,147, the instant method of eliciting a T-cell mediated immune response to transfer factor is disclosed. However, it is an inherent property of Tokoro's method,

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that the animal would elicit a T-cell mediated immune response. Transfer factor would have been present in Tokoro's eggs because the hens would have naturally been exposed to antigens that would elicit a T-cell mediated immune response, such as Newcastle disease virus. Whether or not Tokoro actually knew that transfer factor was present, one of ordinary skill in the art would have known that transfer factor would indeed be present because of natural exposure to the antigens that elicit a T-cell mediated response. Therefore, the method as claimed is anticipated by the prior art of record.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (5,080,895) as applied to claims 1-3, 7-16 and 18-22 above, and further in view of Kirkpatrick *et al* (5,840,700).

The claims are drawn to a method of eliciting a T-cell mediated immune response in an animal by administering an extract of an egg including transfer factor formulated for application to the skin of an animal, nasal administration and parenteral administration. The rejection above establishes the Office's position that transfer factor was inherently present in Tokoro's product. Tokoro is silent on these routes of administration, however, one would have been motivated to use them with the product of Tokoro because Kirkpatrick teaches that transfer factor can be

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administered intravenously, intramuscularly, subcutaneously or orally. Although Tokoro does not explicitly say that transfer factor is present in their product, one would have been motivated to formulate their product for different applications because Tokoro suggests that any appropriate route for administration be used (col. 5, lines 29-34). One would have been motivated to administer the transfer factor via other routes depending on the subject receiving it. One would have had a reasonable expectation of success that the product of Tokoro would have been able to formulate it because Kirkpatrick formulates transfer factor in various mediums. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

### *Conclusion*


6. Claim 17 is free of the prior art of record.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy B. Chen  
November 7, 2003



JAMES HOUSEL 11/15/03  
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